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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,715	08/09/2005	Kristin Wannerberger	052209-0132	5203

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FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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PALENIK, JEFFREY T

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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08/19/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/519,715</p>	<p><b>Applicant(s)</b> WANNERBERGER ET AL.</p>	
	<p><b>Examiner</b> Jeffrey T. Palenik</p>	<p><b>Art Unit</b> 1615</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 11 August 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 1,3,4,6,7 and 13-17.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: See Continuation Sheet.

/Jeffrey T. Palenik/ Examiner  
Art Unit 1615.

/Robert A. Wax/  
Supervisory Patent Examiner, Art Unit 1615

Continuation of 3. NOTE: Applicants' amendments were they to be entered on the record, would require further consideration and/or search on the part of the Examiner. Of particular note is that Applicants narrow the scope of the invention such that the granules, from which the tablet is prepared, must contain: desmopressin, an acid and an excipient. Previously, Applicants recited that the tablet comprised the three ingredients. The amendment introduces a new structural and organizational limitation not previously considered.

Continuation of 5. Applicant's reply has overcome the following rejection(s): Applicants' amendments were they to be entered on the record would be sufficient in overcoming the present grounds rejection of claims 1, 3, 4, 6, 7 and 13-17 made under 35 USC §103, over the teachings of Fein et al. (US Pre-Grant Publication No. 2004/0138098).

Continuation of 11. does NOT place the application in condition for allowance because: Discussed above, Applicants' amendments submitted after final, will not be entered on the record as they contain a structural and organizational limitation not previously considered. The amendment narrows the scope of the dosage form previously recited. Rather than the dosage form simply comprising the drug, acid and excipient in compressed form (e.g. mixed together in any way and compressed together), the claimed invention now recites that the granulate particles from which the tablet is formed, must comprise the three components (i.e., prior to the formation or compression into tablets). Entrance of this amendment into the record would be sufficient in overcoming the present rejection of record, also as discussed above, and would thus require further consideration and search on the part of the Examiner.

Applicants' request for reconsideration of the finality of the rejection of the last Office action, mailed 11 March 2010, has been given the fullest reconsideration, but is not persuasive.

In their Remarks to the previous Final Rejection, Applicants' recite MPEP §706.07(b) stating that "The claims of an application for which a request for continued examination (RCE) has been filed may be finally rejected in the action immediately subsequent to the filing of the RCE". The same passage in the Manual states further that this is proper "where all the claims in the application after the entry of the submission under 37 CFR 1.114 (A) are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114, and (B) would have been properly finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to the filing of the RCE under 37 CFR 1.114."

The Examiner considered Applicants' amendments filed 6 November 2009 and determined that the art of record continued to read upon and render the instant invention *prima facie* obvious.

Applicants' further contest the finality of the previous action, acknowledging on the record that conditions which make it improper to make final a First Office Action on the Merits (FAOM) include where "an RCE where that application contains material which was presented ... after final rejection ... but was denied entry because (A) new issues were raised that required further consideration and/or search, or (B) the issue of new matter was raised."

In the instant case, the Examiner considered Applicants' amendments and concluded that it could be entered on the record and finally rejected as it met both sets of conditions (A) and (B) discussed in the preceding paragraphs.

Therefore, the finality of that action is not withdrawn.